REMARKS

The Official Action of September 1, 2006, and the prior art relied upon therein have been carefully reviewed. The claims in the application are now claims 1-6 and 14-35, and these claims define patentable subject matter warranting their allowance. Accordingly, the applicants respectfully request favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

Claims 4 and 6 have been rejected, as understood, under the second paragraph of §112. The rejection is respectfully traversed.

Claim 4 has been restructured to avoid the criticized word "previously". This claim is intended to cover embodiments where one starts with the bioabsorbable synthetic nonwoven fabric **already containing thrombin**, or one starts with the bioabsorbable synthetic nonwoven fabric and one then first impregnates with thrombin and then later with fibrinogen. This is explained for example on page 8 of applicants' specification, and the method is recited in amended claim 14. As pointed out at page 8, lines 4-6, reaction between the thrombin and fibrinogen is to be avoided until the product is put to use.

With respect to claim 6, its dependency has now been changed to depend from claim 5.

Withdrawal of the rejection is in order and is respectfully requested.

Applicants note for the record that no other rejections have been imposed under §112, whereby applicants understand that applicants' claims are otherwise deemed by the PTO to be in full conformance with §112. Applicants are proceeding in reliance thereof.

Support for the amendment of claim 14 is to be found on page 8 of the specification.

New claim 35 has been added, support being found for example at page 5, line 22; page 6, lines 14-16 and 25; page 7, line 20; and page 9, lines 13-17. New claim 35 is patentable for the same reasons as claim 1 from which it depends, as pointed out below.

Claims 1-6 and 14-34 are rejected under §102 as being anticipated by Greenawalt et al (Greenawalt). This rejection is respectfully traversed.

Specifically, it should be noted that a material used for holding the effective ingredients thrombin and fibrinogen in accordance with the present invention is a bioabsorbable synthetic **nonwoven** fabric. The present inventors have found that a bioabsorbable synthetic material processed in the form of a **nonwoven** fabric made of polyglycolic acid, polylactic acid, a copolymer or glycolic acid with lactic acid or the like may

advantageously by used for a topical hemostatic material since it has an appropriate elasticity and flexibility to ensure valid sealing as well as excellent operability and easy handling.

On the contrary, although Greenawalt discloses a bioabsorbable hemostatic composition comprising a bioabsorbable polymer such as polyglycolide and a hemostatic compound such as thrombin or fibrinogen, it does not teach the use of a material in the form of a **nonwoven** fabric. A reading of Greenawalt suggests that the Greenawalt product is mat-like or cardboard-like, or at best paper-like. There is no indication that such a product has the flexibility and covering characteristics of applicants' product.

Second, applicants note that Greenawalt teaches the use of an **organic solvent**, i.e. a non-aqueous solvent which may be a toxic or unhealthy chemical, e.g. carbon tetrachloride is mentioned as one solvent example. On the contrary, the bioabsorbable synthetic nonwoven fabric of the present invention holding thrombin and fibrinogen is made in such a way as to avoid the use of organic solvent.

Moreover, although the Greenawalt product is not exactly the same as the comparative product against which applicants' nonwoven fabric has been tested (see especially Group 3 on page 12 of applicants' specification, wherein a sponge sheet was used), it is somewhat similar to such a sponge product. Noting Table 1 on page 13 of applicants' specification, it will

be seen that the relatively thick Group 3 product, i.e. the sponge gave very poor results compared with applicants' non-woven fabric.

Thus, the structure of applicants' device is important, as well as the components from which it is made, and the way it is made.

Withdrawal of the rejection is in order and respectfully requested.

Claims 14-16 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 6-8 of co-pending application 10/534,715. The rejection is respectfully traversed.

Claims 14-16 clearly distinguish over the claims of eth co-pending application, as there is no suggestion in the claims of the co-pending application of the use of fibrinogen.

Moreover, applicants believe that the rejection is premature because there are no patented claims. Applicants do not see how there can be any real double patenting until there are patented claims.

Nevertheless, to clear the record without agreeing to the propriety of the rejection, applicants file herewith a Terminal Disclaimer executed by undersigned attorney of record. As such Terminal Disclaimer has been executed by an attorney of record, compliance with 37 CFR 3.73(b) is unnecessary.

Withdrawal of the rejection is in order and is respectfully requested.

The prior art documents of record and not relied upon by the PTO have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of applicants' claims.

Applicants believe that all issues raised in the Official Action have been addressed above in a manner that should lead to patentability of the present application. Favorable consideration and early formal allowance are respectfully requested.

Respectfully submitted,

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